

Appl. No. 10/533,749
Amdt. Dated May 21, 2008
Reply to Office Action of December 21, 2007

AMENDMENT

Ms: Bhisma Mehta

In response to the Official Action dated December 21st 2007 (for which a two-month extension of time is respectfully requested), please amend the above-identified application as follows:

IN THE SPECIFICATION:

In the specification, paragraphs [0006], [0017], and [0039] through [0043] have been amended to correct editorial problems and to address issues presented in the remarks.

IN THE CLAIMS:

Please substitute the following amended claims 1,4 through 8, 11,12,14 through 16, 19, 20, 23 through 32, and 35 for corresponding claims previously presented.

REMARKS

Reconsideration and allowance of the subject application are respectfully requested.

The drawings were objected to as failing to comply with CFR 1.84(P)(5) the specification was corrected to match the drawings, in paragraph 0040 the number 208 is changed to 270, since 270 is the number in the drawings identifying the projecting

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member this change address the objections of both paragraphs 2 and 3 of the office action. This rejection is respectfully traversed.

The specification was objected to noting informalities listed a -d. Each of these informalities is corrected by amendment. This rejection is respectfully traversed

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. Paragraphs 0017, 0042, 0043 are amended to more clearly provide the desired antecedent basis, no new matter was added.

Claims 8-34 were objected to noting informalities. Each of the cited informalities is corrected by amendment. This rejection is respectfully traversed.

Claim 1-3, 5-11, and 14-36 are rejected under USC 102(e) as being anticipated by Ash (US Patent No. 6,958,049). And claims 4, 12, and 13 were rejected under 35 USC 103(a) as unpatentable over Ash in view of Rath et al. It was suggested in the interview with the examiner on 2/11/2008 that amending the apparatus claims to include more than one or a plurality of volume reducers may overcome the prior art. Accordingly to more rapidly advance the application to issuance of patent, independent apparatus claims 1, 5, 14, 19, 27, and 29 and have been amended to replace "at least one volume reducer" with "a plurality of volume reducers" and dependent claims 4, 5, 6, 7, 11, 12, 14, 15, 16, 20, 22, 23, 24, 25, 26, and 28 have been amended to conform to the changes relating to plurality, made to the independent claims. Claims 19 and 29 were further amended to include language pertaining to residual volumes.

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During the interview the examiner indicated that as to claim 32, arguments pertaining to the first, second and third residual volume may overcome the prior art of Ash.

Pursuant this it is noted that Ash teaches the clamping of two extension tubes to prevent leakage of a catheter out the two extension tubes, there is no teaching toward the provision of "a method for intermittently flushing the lumen of an indwelling catheter with flush solution derived from an extension tube in fluid connection with the catheter..." or of the steps of:

- a. injecting flush solution into the extension tube through the sealed proximal terminal to define an initial volume of flush solution within the extension tube,
 - b. after a first delay of at least several hours, reducing the internal volume of the extension tube a first time to force flush solution distally out of the extension tube and along the lumen, thereby defining a first residual fluid volume of flush solution within the extension tube after the internal volume of the extension tube has been reduced the first time, the first residual fluid volume being less than the initial volume,
 - c. after a second delay of at least several hours again reducing the internal volume of the extension tube a second time to force flush solution distally, out of the extension tube and along the lumen, thereby defining a second residual volume of flush solution within the extension tube after the internal volume has been reduced the second time, the second residual volume being less than the first residual volume,
- after a third delay of at least several hours again reducing the internal volume of the extension tube a third time to force flush solution distally, out of the extension tube

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and along the lumen, thereby defining a third residual volume of flush solution within the extension tube after the internal volume has been reduced the third time, the third residual volume being less than the second residual volume.”

There is no teaching in Ash to intermittently flush a catheter with the reduction of the internal volume, indeed in Ash the reduction of the internal volume is performed to prevent leakage and there is not teaching of leaving one of the clamps of Ash open to be used after a first delay for flushing. Ash’s method of preventing leakage by closure teaches away from the method of intermittently flushing by sequential volume reduction after sequential delays. There is further no teaching in Ash for the defining of a plurality of residual volumes of the extension tube after sequential delays, much less a first, second, and third residual volumes after sequential delays. The function of preventing leakage teaches away from delaying the closure of the clamps of Ash after the injection of flush solution into the extension tubes of Ash.

Accordingly step c of independent method claim 30 has been amended to comprise the step of: “progressively reducing the internal volume of the tubing system to displace at least sequential portions of the residual volume into the indwelling portion to intermittently flush the indwelling catheter portion with the flush solution, wherein the steps of progressively reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and reducing the volume of the single extension tube a second time to thereby define a second

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residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.”

Similarly step d. of independent method claim 31 has been amended to comprise the step of: “sequentially reducing the internal volume of the extension tube a plurality of different times to displace sequential portions of the residual volume of the flush solution into the lumen to flush the lumen with the flush solution so that patency of the lumen is maintained for an extended period of time, wherein the steps of sequentially reducing comprises reducing the volume of the single extension tube a first time, to thereby define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.”

Similarly independent method claims 35, was amended to claim “a method of maintaining the patency of a lumen of an indwelling catheter over a 24-72 hour period, the lumen being connected with a single fluid locked extension tube filled with flush solution, the extension tube defining an internal volume, the method comprising steps of; sequentially reducing the internal volume of the extension tube a plurality of different times to express sequential portions of the flush solution from the extension tube into the lumen to sequentially flush the lumen at a plurality of different times, wherein the steps of sequentially reducing comprises reducing the volume of the single extension tube a

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first time, to thereby define a first residual volume of the extension tube, and without refilling the extension tube, reducing the volume of the single extension tube a second time to thereby define a second residual volume of the extension tube, the second residual volume of the extension tube being less than the first residual volume of the extension tube.”

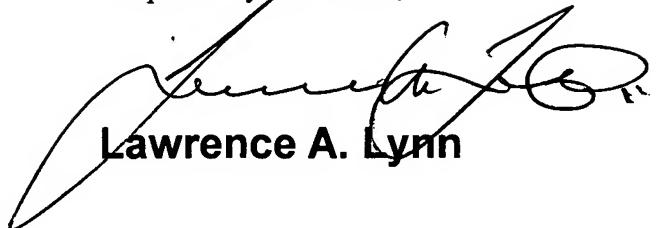
Nowhere does Ash teach, or in combination with any prior art document, render obvious the methods as claimed in fact Ash teaches away from the methods as claimed. Claims 1, 5-26, 29, and 30 were rejected on the grounds of non statutary double patenting over US Patent 6,689,109. A terminal disclaimer was filed on Sept. 10, 2007. but was not accepted because the assignee has not established its ownership interest in the patent. However neither the instant application nor US Patent 6,689,109 has been assigned and both are 100% owned by Lawrence A. Lynn the sole inventor in both US Patent 6,689,109 and the instant application. This was formally attested in the terminal disclaimer filed on Sept. 10, 2007. If additional proof of ownership is required the applicant respectfully requests the favor of a phone call or informative action indicating the nature of the proof required.

It is respectfully submitted that this application is now, in condition for allowance. Should the Examiner believe that anything further is desirable in order to place the

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application in even better form for allowance, she is respectfully petitioned to telephone the applicant at the below-listed number.

Respectfully submitted,



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